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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,211	03/25/2002	William E Hintz	2847-62447	4982

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,211

Applicant(s)

HINTZ ET AL.

Examiner

David J Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

- [1] Claims 1-14 are pending in the application.
- [2] It is noted that claim 14 recites a mannosidase identified by the method of claim 13. However, claim 13 is drawn to a method for isolating a nucleic acid and not a mannosidase. For purposes of advancing prosecution, claim 14 has been included in Group I as though the claim were drawn to a protein. It is suggested that applicants clarify the meaning of the claim.

Lack of Unity

- [3] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Groups I-III, claim(s) 1, 8-9, 12, and 14, drawn to the special technical feature of a protein having mannosidase activity and variants thereof and the first claimed method of use, *i.e.*, a method for altering the glycosylation pattern of a macromolecule. Group I recites SEQ ID NO:3, Group II recites SEQ ID NO:6, and Group III recites SEQ ID NO:18.

Groups IV-VI, claim(s) 2, drawn to the special technical feature of a specific binding agent. Group IV recites an agent that binds SEQ ID NO:3, Group V recites an agent that binds SEQ ID NO:6, and Group VI recites an agent that binds SEQ ID NO:18.

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Groups VII-IX, claim(s) 3-7 and 10-11, drawn to the special technical feature of an isolated nucleic acid, a recombinant nucleic acid, a transformed cell, a transgenic fungus, and the first claimed method of use, *i.e.*, a method for producing a macromolecule having an altered glycosylation pattern. Group VII recites a nucleic acid encoding SEQ ID NO:3 including SEQ ID NO:1, Group VIII recites a nucleic acid encoding SEQ ID NO:6, including SEQ ID NO:4, and Group IX recites a nucleic acid encoding SEQ ID NO:18, including SEQ ID NO:17.

Groups X-XII, claim(s) 13, drawn to the special technical feature of a method for isolating a nucleic acid sequence. Group X recites SEQ ID NO:1, Group XI recites SEQ ID NO:4, and Group XII recites SEQ ID NO:17.

[4] The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

According to PCT Rule 13.2 unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The nucleic acids of Groups VII-IX, the polypeptides of Groups I-III, and the binding agents of Groups IV-VI share no special technical feature as the nucleic acids of Groups VII-IX, particularly the nucleic acids of claim 11, encompasses nucleic acids that do not correspond to the polypeptide of Groups I-III and instead encompass nucleic acids that would encode polypeptides that would not bind to the binding agent of Groups IV-VI.

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have

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a common structure. Although the polypeptides of Groups I-III, the polynucleotides of Groups VII-IX, and the binding agents of Groups IV-VI may share a common property or activity, the compounds are not regarded as being of similar nature because all alternatives do not share a common structure.

The polypeptides of Groups I-III and the binding agents of Groups IV-VI do not have unity of invention with the methods of Groups X-XII as the polypeptides and binding agents are neither made nor used by the methods of Groups X-XII.

37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention. Accordingly, the methods of Groups X-XII do not have unity of invention with the nucleic acids of Groups VII-IX.

According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions of Groups I-XII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Groups I-III is a polypeptide, which is shown by Inoue et al. (*Biochem Biophys Acta* 1253:141-145; cited in the IDS filed March 25, 2002) to lack novelty or inventive step because Inoue et al. teach a polypeptide that is greater than 60% identical to SEQ ID NO:6 and does not make it a contribution over the prior art.

[5] Claims 1-14 will be examined only to the extent the claims read on the elected subject matter.

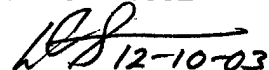
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[6] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[7] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652


12-10-03
DAVID STEADMAN
PATENT EXAMINER